NOMINATIONS OF MATTHEW N. NOVICK AND JOHN A. TODHUNTER

HEARINGS

BEFORE THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

FIRST SESSION

ON

THE NOMINATIONS OF MATTHEW N. NOVICK TO BE INSPECTOR GENERAL, ENVIRONMENTAL PROTECTION AGENCY, AND JOHN A. TODHUNTER TO BE ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

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NOMINATION OF MATTHEW N. NOVICK

TUESDAY, SEPTEMBER 22, 1981

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, D.C.

The committee met at 10:05 a.m., in room 4200, Dirksen Senate Office Building, Hon. Robert Stafford (chairman of the committee) presiding.

Present: Senators Stafford and Randolph.

Senator STAFFORD. The Committee on Environment and Public Works will come to order.

This morning we will hold a hearing on the nomination of Mr. Matthew N. Novick to be Inspector General of EPA.

We are very glad to welcome you here, Mr. Novick. We suggest you come to the witness table and we would be very happy at this point to hear any statement you may wish to make to the committee; unless, first, Senator Randolph has an opening statement.

Senator RANDOLPH. Mr. Chairman, I have no opening statement. I think that we just should proceed. Then if we feel questions are necessary or advisable, we would ask them to respond. Thank you.

Senator STAFFORD. All right. Mr. Novick, we will be glad to hear you.

STATEMENT OF MATTHEW N. NOVICK, NOMINEE TO BE INSPECTOR GENERAL, EPA

Mr. NOVICK. Thank you, Mr. Chairman.

I would like to submit my statement and my biographical sketch for the record, and I would like to make a few summary remarks, if I may.

Senator STAFFORD. Without objection, your résumé and your full statement will appear in the record, and you may say whatever you wish in addition. (See p. 5.)

Mr. NOVICK. Mr. Chairman, I am particularly pleased and honored to appear before you today as President Reagan's nominee for Inspector General of the Environmental Protection Agency.

I sincerely believe that the Inspector General Act has created a rather unique approach in the Government's efforts to ferret out fraud, waste, abuse, and mismanagement and, if confirmed as the Inspector General of the Environmental Protection Agency, I intend to carry out the objectives of the act to the best of my ability.

As a result of more than 20 years of Federal experience in accounting, budget, and audit functions, I have seen tremendous and unquestioned need for the independent and objective analysis of Government programs and operations. My varied professional

experience has given me the unique opportunity to assess the weaknesses and pitfalls of the Federal Government from within. This overall experience should enable me to determine when the limited audit and investigative resources of the Inspector General of the Environmental Protection Agency may be most effectively and efficiently utilized.

Thank you.

Senator STAFFORD. Mr. Novick, do you know of any interests which you may hold personally or through members of your family or in any otherwise of a beneficial nature which might create a conflict between the carrying out of your duties and obligations as Inspector General of the Environmental Protection Agency?

Mr. NOVICK. No, sir.

Senator STAFFORD. Are you willing to appear and testify when asked before this or any other committee of the Congress?

Mr. NOVICK. Absolutely.

Senator STAFFORD. I don't believe, Senator Randolph, that I have any further questions to direct to this nominee myself. If there are some from other members of the committee, it would be my purpose, if you are agreeable, Senator Randolph, to permit a day in which written questions might be submitted to Mr. Novick for an immediate written response, so we can get this matter to the Senate. But if I hear of no request of written questions by, say, 3 this afternoon, we will assume there will not be any.

Having said that, Senator Randolph, do you have questions?

Senator RANDOLPH. Briefly, Mr. Chairman.

First of all, I would like to ask you, What are your duties in the position that you have been nominated for.

Mr. NOVICK. Briefly, Senator, the functions of the Inspector General will be to manage the audit and investigative activities which oversee the programs and funds of the Environmental Protection Agency.

In that regard, I independently will establish workload plans to do just that. It involves not only management audits, it involves audits of a cost-type dealing with the construction projects. It deals with questions of whether the programs are being effectively and efficiently managed. And it deals with whether funds are being used for the purposes intended.

It involves a wide range of oversight over the Environmental Protection Agency, both for the Congress and for the President. It is basically that function.

Senator RANDOLPH. In other words, you audit and monitor the expenditures of EPA money in the field; is that correct?

Mr. NOVICK. Correct, sir; both the contracts and those moneys which are spent in-house.

Senator RANDOLPH. Do you enter into any policy decisions of the kinds of programs or projects the agency carries forward?

Mr. NOVICK. The law requires, sir, that the Inspector General advise the Administrator and recommend changes to policy. But the Inspector General is not authorized to make policy. I simply recommend changes to policy.

Senator RANDOLPH. What do you envision as the type of changes that your position would permit or encourage you to make?

Mr. NOVICK. Policies which may enhance internal control. Policies which may better utilize the limited resources that will be available to the EPA. Policies that would be of that nature.

Senator RANDOLPH. I think the second one you mentioned is very important. In other words, the wise expenditure of the funds you have for the work that is necessary for the agency.

Mr. NOVICK. Yes, sir. The law requires that the Inspector General determine how effectively and efficiently programs are being administered. The IG is concerned with the economy of programs and, as a result, could recommend changes to policy that affect that.

Senator RANDOLPH. Mr. Novick, you have given to the committee your résumé. Would you tell us what your background is and your qualifications for the particular position?

Mr. NOVICK. I have 23 years of Federal experience, going back to 1961, when I became an auditor with the Army Audit Agency. In that respect I was doing financial management audits for the Army, and management audits at the Corps of Engineers. In essence, I performed audits dealing with internal control of finances and the management decision process to verify that the corps programs were in fact complying with military construction laws.

From that point, I moved to the Office of the Secretary of Defense where I joined the Defense Audit Service and continued my career in the audit profession. In total, I moved from GS-9 to GS-15 as an auditor and held virtually every position that was available to me through those grade ranges.

In 1970, I was recommended for a year in post-graduate study at the Industrial College of the Armed Forces, which I completed in 1971. And in September of 1971 the Secretary of Defense recommended me for a senior budget analyst position in the Comptroller's office. For 3 years I was a senior budget analyst dealing with major weapons systems procurement.

In 1974, I was selected by the Secretary of the Interior to be his financial manager, and in that capacity I managed the finance accounting and budget responsibilities for that office.

In 1977, I was selected through competition to be Deputy Director for the Office of Territorial Affairs where I was responsible for the management of the internal audits of the territories, which was performed by the U.S. Government comptrollers, and for the finance, administration, and budget of the territories.

In 1980, I was promoted to be Director of Technical Assistance in the Office of the Assistant Secretary for Territorial Affairs and charged with the responsibility of improving financial management information systems for the territorial governments.

I have had that job, sir, until this year when I was selected by the President to be nominated for the Inspector General of the EPA.

Senator RANDOLPH. Chairman Stafford, I asked that Mr. Novick do this because seldom, as I recall, have we had a nominee come and sit at that table who has been so ready and has the background to describe exactly what he has done in connection with the kind of job that he now will be expected to do. He has not dealt in generalities. He has spelled it out. It is very comforting to me to

see especially in a position where you are charged with the handling of the finances, which is the taxpayers' moneys; is that right?

Mr. NOVICK. Yes, sir.

Senator RANDOLPH. You have a very real responsibility, which you are ready to assume.

Mr. Chairman, I do not want to presume on procedure, but I make a suggestion. I would like the opportunity now or at a later time to move favorably his nomination from this committee to the Senate. I realize that we cannot vote upon it without a certain number of members who are either present or coming to the committee to let their desire be known. Unless by unanimous consent, the committee agrees to poll the members. So you have certain options and alternatives which you can follow. I only suggest that whatever option or alternative is followed, I be given the opportunity, as I asked, to move the nomination.

Senator STAFFORD. Thank you very much, Senator Randolph. The Chair would rule that it would be appropriate for you to move confirmation of Mr. Novick now and the matter will be set on the agenda for a meeting of the committee, at which we anticipate a quorum will be present. At that time it could appear that Mr. Novick would already be nominated and in a position for us to vote at once.

Senator RANDOLPH. Yes. I think that is agreeable.

Senator STAFFORD. So if you will so move, the Chair will have that noted in the record.

Senator RANDOLPH. Mr. Chairman, I move that the committee favorably report to the Senate the nomination of Mr. Novick.

Senator STAFFORD. All right.

Before we close, the Chair also certainly has been impressed with your outstanding record, Mr. Novick. As we indicated at the outset, it will be a part of the printed record so that members will have a chance to examine it.

I think I want to emphasize that the absence of the members of the committee here this morning has two factors. One is other busy committees detract from our attendance. But the real one is that there is no opposition we know of to your nomination and general approval. If there were a number of committee members here, it would be for the purpose of asking questions and possibly opposing your nomination. So I think while the attendance is light, it is a good sign as far as your being confirmed is concerned.

Not entirely seriously, the Chair did note that you have had unique opportunity to assess the weaknesses, pitfalls, and vulnerabilities of the Federal Government from within. As an extracurricular activity, Senator Randolph and I might ask you to advise us informally as to such pitfalls and vulnerabilities we might face that we should avoid in the future.

Mr. NOVICK. I would be delighted to, sir.

Senator STAFFORD. I think that will close the hearing as far as Mr. Novick is concerned, if that is agreeable to you, Senator Randolph.

Senator RANDOLPH. Yes.

Mr. NOVICK. Thank you, Senator, Thank you, Mr. Chairman.

[Mr. Novick's prepared statement and biography follow:]

STATEMENT OF

MATTHEW N. NOVICK

INSPECTOR GENERAL-DESIGNATE

Mr. Chairman, members of the Committee, I am particularly pleased and honored to appear before you today as President Reagan's nominee for Inspector General of the Environmental Protection Agency. I welcome this opportunity to share with you my observations and concerns with respect to the prevention and detection of fraud, waste, abuse and mismanagement in government programs and operations.

I believe that it is important and appropriate to state for the record my personal and professional view of the Inspector General Act of 1978. I sincerely believe that the Inspector General Act has created a rather unique approach in the government's efforts to ferret out fraud, waste, abuse and mismanagement and if confirmed as the Inspector General of the Environmental Protection Agency, I intend to carry out the objectives of the Act to the best of my ability.

As you are well aware, the duties and responsibilities of the Inspector General are clearly delineated in the Act. As independent and objective units, the Office of Inspector General must:

(a) conduct audits and investigations relating to programs and operations at EPA;

(b) recommend policies to promote economy, efficiency and effectiveness with respect to those programs and operations and to detect fraud and abuse; and finally

(c) keep the Administrator and the Congress informed about problems and deficiencies relating to the administration of such programs and the necessity for corrective action.

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I read the Act literally and I believe that the Inspector General must vigorously pursue and adhere to these responsibilities if the Office of Inspector General is going to have a significant and beneficial impact on Agency programs and operations. What is particularly important is the fact that I do not believe that it should be the sole objective of the Office of Inspector General to merely identify and detect fraud, waste, abuse and mismanagement; it is equally important that we lend our expertise to promote economy and efficiency that could result in tremendous savings to the government. That is the determinant which should also be used to ascertain whether we are successful in our efforts.

As a result of more than 20 years of Federal experience in accounting, budget and audit functions, I have seen on innumerable occasions the tremendous and unquestioned need for the independent and objective analysis of government programs and operations now the responsibility of the Office of Inspector General. It is axiomatic that the Inspector General of any Federal agency must firmly grasp the reins of leadership of his or her particular unit and commit his or her available audit and investigative resources to the unenviable task of promoting a greater amount of economy and efficiency. I view this as our mandate and I intend to pursue vigorously this objective if confirmed.

In conclusion, I would like to state that my varied professional experience has given me the unique opportunity to assess the weaknesses, pitfalls and vulnerabilities of the Federal government from within. This overall experience should enable me to determine where the limited audit and investigative resources of the Inspector General of the Environmental Protection Agency may be most effectively and efficiently utilized.

I would be pleased and I welcome any questions that you or other members of the Committee might have.

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Biographical Sketch

Matthew N. Novick
Inspector General, EPA Designate

Matthew N. Novick has had over 20 years of Federal experience in accounting, budget and audit functions.

Mr. Novick joins the Environmental Protection Agency from the Department of Interior where, since July 1980, he has served as the Director of Technical Assistance for the Office of the Assistant Secretary for Territorial and International Affairs. In this capacity, Mr. Novick initiated a framework to improve the areas of budget formulation, accounting systems development, economic development, and middle management training in all areas required by the territorial governments.

Mr. Novick's experience in Federal audit functions began in 1961 when he worked as a journeyman auditor and later a supervisory auditor for the U. S. Army Audit Agency. He spent approximately 4 years with the U. S. Army Audit Agency conducting audits of Army contractors, Army funded university R&D programs, and the activities of the Corps of Engineers.

In 1964 Mr. Novick joined the Office of the Secretary of Defense Audit Service as a supervisory auditor and was quickly promoted first to be audit manager and then to be chief of the Major Acquisition Audits Division. During his 7 years with the Defense Audit Service he planned, initiated and supervised many comprehensive and functional audits within the Office of the Secretary of Defense and the Joint Chiefs of Staff. These audits included the identification of significant findings and the potential for great savings in such areas as weapons procurement, financial management practices, ADP systems control, major weapon systems development and the effective accomplishment of management mission objectives.

To broaden his experience in budget formulation, and because of his expertise and knowledge of the DOD acquisition process for major weapon systems, Mr. Novick was selected in 1971 to be a Senior Budget Analyst in the Office of the Assistant Secretary of Defense (Comptroller). During the next 3 years Mr. Novick directed and coordinated the formulation and execution of the DOD budgets related to the procurement of tactical missiles, communication equipment, tactical support vehicles and electronics equipment for the Army, Marine Corps and Defense Agencies, which totalled approximately $19 billion per year.

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In 1974 Mr. Novick joined the Department of Interior as Financial Manager and Chief Fiscal Officer for the Office of the Secretary. For the next 3 years he supervised all aspects of the budget process from initial development to presentation before the Congress and a full range of financial activities for the Office of the Secretary of Interior and its related agencies. In this capacity he managed a staff of 44 people and administered approximately $20 million annually in direct appropriations.

In 1978 the Secretary of Interior established the position of Deputy Director of Finance and Administration for the Office of Territorial Affairs. Mr. Novick competed for and was selected for this supergrade position. During the following 3 years Mr. Novick was responsible for financial oversight and internal audit of all funds which flowed to the treasuries of Guam, the Northern Mariana Islands, American Samoa, the Virgin Islands and the Trust Territory of the Pacific Islands. This responsibility included the management and supervision of a professional Federal audit organization composed of 82 individuals with regional offices in each territory headed by a Federal Comptroller. In this capacity, Mr. Novick's primary responsibility was to have audits conducted of all Federal funds so as (1) to improve the efficiency and economy of the programs and activities of the various governments, and (2) to insure that the substantial Federal revenues which were transferred to the treasury of the territorial governments were properly accounted for and spent only for the purposes intended.

Mr. Novick graduated from Benjamin Franklin University with a degree in Accounting in 1963. He has had extensive training in accounting and auditing, data processing, systems design, budget and finance and management during his Federal career. In 1971, he attended and completed a year of post graduate study in industrial management at the Industrial College of the Armed Forces at Fort McNair, Washington. While at the Department of Interior, he was awarded two Quality Pay Increases for meritorious performance and received numerous outstanding performance awards and letters of commendation for excellent service. Mr. Novick is a Certified Internal Auditor, issued by the Board of Regents of the Institute of Internal Auditors. In January, 1981, he was elected to the Board of Directors of the Association of Government Accountants - Prince Georges-Montgomery Chapter.

Mr. Novick was born in 1933 in Brooklyn, New York. He married Judith Ann Peikin of Washington, D. C. in 1958. They are the parents of three children: Robert, a junior majoring in Economics and Public Administration at the University of Maryland; Laura, a freshman majoring in Business Administration at the University of Maryland; and Karen, who is entering the 10th grade at Winston Churchill High School in Potomac, Maryland.

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NOMINATION OF JOHN A. TODHUNTER

FRIDAY, OCTOBER 16, 1981

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, D.C.

The committee met at 10:05 a.m., in room 4200, Dirksen Senate Office Building, Hon. Robert T. Stafford (chairman) presiding.

Present: Senator Stafford.

OPENING STATEMENT OF HON. ROBERT T. STAFFORD, U.S. SENATOR FROM THE STATE OF VERMONT

Senator STAFFORD. The Committee on Environment and Public Works will please come to order.

I will say good morning to our guest.

This hearing of the committee is being held to consider the nomination of Dr. John A. Todhunter to become Assistant Administrator of the Environmental Protection Agency. This is the third Assistant Administrator nomination which this committee has considered.

We are most pleased to have this nomination before us. We look forward to receiving the remaining Assistant Administrator nominations so that EPA can be fully operational at the administrator level. We think that is important.

Dr. Todhunter's nomination is for Assistant Administrator for the important office of Toxic Substances. I say "important" because I feel that it is important to this committee and to the public. This committee has been responsible for much of the legislation, including the Toxic Substances Control Act, which Dr. Todhunter will be called to administer if he is confirmed. Quoting from TSCA, "Among the many substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health and the environment."

It is those chemical substances and mixtures which it will be Dr. Todhunter's responsibility to identify and regulate. That responsibility should not be taken lightly, and I don't believe it will be.

Dr. Todhunter, we welcome you to our hearing today. We also welcome your wife, Charlsie, who is here with you.

You may proceed with your remarks whenever you are ready.

STATEMENT OF JOHN A. TODHUNTER, NOMINEE TO BE ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Mr. TODHUNTER. Thank you, Mr. Chairman.

Mr. Chairman, I come before you to discuss my nomination by President Reagan to be the Assistant Administrator for Pesticides and Toxic Substances of the Environmental Protection Agency. My own reaction to this nomination was a sense of being honored by this public trust. The reaction of my friends and family was a more sober assessment of the burden I was willing to accept in the public's service.

My being here before this committee is a first for EPA in that you see before you a scientist. The language of TSCA, the Toxic Substances Control Act, describes the Assistant Administrator for Toxic Substances as a person qualified by training and experience to direct a program in chemical safety. Administrator Gorsuch, in selecting me for nomination, is acting to fulfill the intent of the law. This is consistent with her actions on other staff positions in EPA. She has sought out technically trained and talented people to help manage the Agency. Dr. John Hernandez, the Deputy Administrator, and Dr. Andrew Jovanovich, Acting Assistant Administrator for Research and Development, exemplify this commitment to technically able managers for what is, at heart, a science and technology-based Agency.

I see my nomination as an opportunity to contribute to two goals which, I believe, are vital to the future of EPA: Protection of the public health and the environment and the cultivation of sound science as a data base for regulatory decisionmaking. I would like to briefly expand on these two areas.

The Environmental Protection Agency is the lead Federal agency in the protection of our environmental heritage and in protection of human health as it is affected by the physical environment. I am personally committed to these goals. I, and other senior EPA managers, am also committed to achieving goals in the way which do not overly burden the taxpayer or our economy relative to the effects realized as a result of our regulatory stances.

We enjoy, in the United States, a rich environmental heritage. We also enjoy a standard of health in which we can take pride. Over the last 10 years, we have seen continuing discussion and an evolving definition of the relationship of Americans to their environment. We have come to learn that the environment is at times benevolent and, at times, less than benevolent. We have been coming to grips with the enormity of the interdependence between humans and the environment. We have come to a sensitivity that fouling of the environment is not a private act but one which can compromise the rights of our neighbors.

We have also, I hope, come to an awareness that not every human interaction with the environment constitutes an adverse impact. Living with, cherishing, conserving, and passing on to our heirs the environment does not require that we embalm the environment. There is ample room for concordance of activities in a technological/industrial society with the aim of health and environmental protection.

Congress has wisely recognized this fact in both TSCA and FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act, the two major acts administered by the Assistant Administrator for Pesticides and Toxic Substances. Both of these laws are risk balanc-

ing statutes. They do not speak of absolute risk or zero risk but of reasonable versus unreasonable risk.

This question of reasonable versus unreasonable risk brings me to my second major goal: The use of sound science in the decision process. Too often, our understanding of the risk side of the risk/benefit equation rests on faulty or incomplete grounds. We need a better data base. We need to see a return of informed professional judgment to an area which has been abdicated to "risk" numbers generated by computer curve fitting programs. We need to see an attempt to apply our developing knowledge of toxicological and physiological principles to the interpretation of risk data.

What I would strive for as Assistant Administrator is a sense of credibility and reasonableness in what the Office of Pesticides and Toxic Substances does.

I am seeking the opportunity to administer TSCA in an integrated fashion which will provide both a greater measure of public and environmental protection as well as a reduction in the complexity of toxic substances regulations and the burden of these regulations of the regulated community.

With FIFRA, I am again seeking the opportunity to administer the law so as to improve public and environmental safety while insuring theat FIFRA regulations are structured so as to not discourage the development of those products needed to support our efforts to raise food and protect our citizens.

I am also supportive of Administrator Gorsuch's policies regarding greater involvement by the States. EPA has had a long history of looking down its nose at State agencies. I would like the opportunity to change that attitude in the Office of Pesticide and Toxic Substances.

In concluding these brief introductory remarks I would like to place a note of personal priority on some of the goals and issues I have raised. The No. 1 concern, to me, comes down to that of the public health, safety, and well-being.

Thank you for your kind attention.

I would be very happy to answer questions which the committee wishes to address to me at this time.

Senator STAFFORD. Thank you very much, Doctor.

Let me, before I get to the questions, make one observation for the committee. All of the laws administered by the Environmental Protection Agency require actions to be taken in instances where our knowledge base is somewhat uncertain. But that is likely to occur more in your area than any other. And the consequences of an incorrect decision have great potential for disaster in your area, more so than any other area, as I am sure you are aware.

Finally, all of these other laws required that decisions in the face of uncertainty err on the side of caution. Congress has mandated that regulatory response to ignorance be decided in favor of protecting the health, not threatening it. In no area is that more so than in the position for which you are nominated, as I am sure you are aware.

Let me ask you, as we always do for this committee, if the committee reports favorably on you and the Senate confirms you, are you prepared to come before any committee of the Senate that may ask you to come as a witness?

Mr. TODHUNTER. Yes, I am.

Senator STAFFORD. And you make that statement without reservation?

Mr. TODHUNTER. I do so.

Senator STAFFORD. Are you aware of any interest that you or your immediate family might have that would put you into a conflict of interest position as far as your duties may occur if you are confirmed?

Mr. TODHUNTER. No, Mr. Chairman, I am not.

Senator STAFFORD. All right, very good.

Under the previous administration, the risk assessment process used to determine whether regulation of the substance was appropriately involved, among other things, the evaluation of the hazards of occupational exposure to substances and with respect to an evaluation of carcinogenisis—if I get that $10 word correct, for most of us it means cancer-causing agents—an assumption that man would be exposed to the evaluated substance throughout his lifetime.

Do you envision that risk assessments which you will be called upon to perform will involve those considerations? Would you go on to fully explain your approach to risk assessment, including your underlying assumption?

Mr. TODHUNTER. Yes, Mr. Chairman, I would.

The basis for risk assessment which has been used by the Agency in the past has been, and will continue to be, the use of animal test data. This is a sound, established toxicological principle. We have no other way to generate this type of assessment. It is unethical to expose humans to a carcinogen to determine if in fact it presents an adverse effect.

What perhaps may change is the Agency's practice of assessing data only using one of several available computer curve fitting models which try to give some mathematical form to the test data.

Speaking as a scientist, that isn't the soundest way to evaluate what the level of risk might be. Most of those models, if they are applied to the same data, give you estimates which vary. Generally some of the models will agree, and where models agree, you might have greater confidence in what you are coming up with as a relative risk.

I don't think, however, that you will see major differences between myself and the practice of the Agency in the past as to the use of animal data.

Senator STAFFORD. "The American Council on Science and Health, of which you have been a member, is an independent educational association promoting scientifically based evaluation of chemicals, the environment and human health."

That quotation was taken from the cover of several American Council on Science and Health publications. What does "scientifically based evaluation" mean?

Mr. TODHUNTER. Generally that is taken, at least it has been taken by the Council with which I was associated, to mean that in placing a particular public health issue into perspective, it is necessary to use all of the existing data, not to select from the data according to what result you want to come out with. The Council generally has tried to address public health issues by going

through the process of reviewing the world literature on a particular item, and contacting researchers who are in the forefront of those fields. The Council's practice has been, and continues to be, to prepare a position statement on a particular issue. That statement is reviewed internally in the Council and then, as a further quality assurance, is reviewed externally by people not associated with the Council, but who are recognized experts in the field.

Senator STAFFORD. Thank you, Doctor.

The National Cancer Institute's Report on U.S. Cancer Deaths, including the Cancer Atlas, indicated a correlation between cancer mortality or local or regional urbanization. The American Council on Science and Health publication, "New Jersey, Garden State or Cancer Ally"—it didn't say that about Vermont—printed most recently in April of this year, and commented on by you, argued about the relationship between urbanization and cancer is "complex" and that it is likely that accumulation of risk factors, including smoking, alcohol use, and dietary practices, genetic traits, and occupational hazards contribute in the relationship.

Does the American Council on Science and Health intend to rebut the urbanization-cancer relationship or merely explain it? Why would the Council do either, as a matter of fact?

Mr. TODHUNTER. The Council did not intend so much to rebut as to interpret. The Council attempted this for the simple reason that that is what the Council was created to do, to provide a mechanism whereby people in the media and public life could have access to interpretive information. I think that the National Cancer Institute paper to which you are referring is one of many papers in the field of the relationship between urban life and cancer. Generally there appears to be some scientific debate over whether that is a real phenomenon or not.

Senator STAFFORD. Thank you, Doctor.

You have been listed as a policy adviser on previous American Council on Science and Health publications. May I ask, what is a policy adviser? Is there any inconsistency between the Council policies and current EPA policies and previous EPA policies?

Mr. TODHUNTER. I was not a policy adviser to the Council. I was a scientific adviser to the Council. There are policy advisers; I am not one of those.

The role of a scientifc adviser to the Council involves the review of Council materials, in some particular instances the coordination of review studies. In my work with the Council, I generally did not become involved in EPA issues except on one occasion in which I did not contribute to the report but helped to interpret the report that was prepared.

Senator STAFFORD. For Senator Randolph, who unavoidably cannot be here today, let me ask this question in his behalf.

It is important that even the appearance of possible conflicts of interest be avoided for an officer whose responsibilities often include making adjudicatory decisions about the registration of uses of substances. Because of your association with the American Council on Science and Health and the industry-supported group which has taken an advocacy role on the use of 2,4,5–T and your involvement in formulating that position, will you excuse yourself from taking part in any decision, negotiation or actions affecting 2,4,5–T,

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which Senator Randolph must know but certainly the chairman doesn't?

Mr. TODHUNTER. I would like to take this opportunity to clear up a great deal of misunderstanding which has appeared in the press about my relationship to 2,4,5–T and the Council. I was not a contributor to the position paper which the Council prepard on 2,4,5–T. My whole involvement with the Council and 2,4,5–T was to be part of a panel which was put together at the time that the position paper of the Council was released. My role was basically to answer questions relating to toxicology and things like that.

The Council also, to my knowledge, has not taken an advocacy position on 2,4,5–T. The Council is not an advocacy group. Their general approach has been, and in the case of 2,4,5–T was, I believe, solely to generate and release a position document, and as far as I know, that is where the matter dropped.

Senator STAFFORD. Doctor, I think it would clear the record and help the chairman of this committee and the other members besides Senator Randolph if you briefly describe what 2,4,5–T is.

Mr. TODHUNTER. Yes, 2,4,5–T is tricholorophenoxy acetic acid, that is a herbicide agent which has been used in this country for 30 years. As a mixture with 2,4–D, it is agent orange, which was used in Vietnam. I would like to emphasize that the review of the Council on 2,4,5–T has no bearing or relationship whatsoever to use of agent orange in Vietnam because we have no information as to exposure or use conditions in that country.

Senator STAFFORD. Irrespective of what your role might or might not have been with respect to 2,4,5–T, will you excuse yourself from taking part in any decision or negotiation or action which might affect it in the future?

Mr. TODHUNTER. I have indicated before my nondesire to become involved in those proceedings. They are under negotiation with the Office of the General Counsel. It is my understanding that Dr. Hernandez has the lead in that and it is not my intention to become involved at this time.

Senator STAFFORD. In othe words, you won't take part in any activity with respect to that particular pesticide.

We have reviewed your distinguished career in academia. You are currently chairman of the biochemistry program of the Catholic University?

Mr. TODHUNTER. I am currently on leave to function as a consultant to the administrator.

Senator STAFFORD. That has been your last academic assignment?

Mr. TODHUNTER. For the last 3 years.

Senator STAFFORD. And you have a Ph. D. in biochemistry from the University of California in 1976?

Mr. TODHUNTER. That is correct.

Senator STAFFORD. Without objection, the chair sees nobody here to object, the chair will put your entire résumé in the record. (See p. 20.)

I think, Doctor, that we have adequately questioned you here for the committee and I have discussed this matter with you in my office earlier.

The chair is going to reserve the right for a couple of days for other members of the committee who couldn't be here today to submit questions to you in writing if they care to do so. And we would ask for your very early response in order to expedite the time when the committee might be able to vote on your nomination.

Mr. TODHUNTER. I will be more than happy to respond.

Senator STAFFORD. Thank you, that will be all for today and we are glad to have you here with us.

We are likely to see more of you in the future.

Mr. TODHUNTER. Thank you.

Senator STAFFORD. The committee is advised that we have another withness this morning before closing the hearing, Jacqueline M. Warren of the Natural Resources Defense Council. We would be glad to here from you at this point.

I know you have a long statement that is in the hands of the committee. I would invite you to summarize it and we will put the entire statement in the record as if read, or you may read it if you wish.

STATEMENT OF JACQUELINE M. WARREN, NATURAL RESOURCES DEFENSE COUNCIL

Ms. WARREN. I have been involved with the area of toxic substances regulations for the past 8 years. For 7 of those I was staff attorney for the Environmental Defense Fund, and now I am Director of the Natural Resources Defense Council's Toxic Substances Project. During that time I have been involved with FIFRA and I have also worked from the time of passage of TSCA through its implementation.

Senator STAFFORD. Do you have a scientific background?

Ms. WARREN. No, I am an attorney. I have Ph. D. scientists on the staff and have had them at both organizations, as well as outside scientists to assist with this work.

Some of the concerns I wanted to address this morning have been expressed, but I still want to make the main points that I have in my testimony.

One of the real concerns that I have had, and I have been over the last several years a very outspoken critic of the slow pace of EPA's prior administration of TSCA is the fact that too few actions were taken under the statute. I feel we are only on the threshold of effective regulation of toxic substances rather than that we have done quite enough and that it is time to retune and refine. We have done almost nothing on toxic substances under the Clean Air Act or the Clean Water Act. We have not really implemented the hazardous waste program.

I observe things happening at EPA now which suggest to me that the slow amount of progress that had been made is in danger of being reversed and that the prospects of making TSCA what it was designed to be are not very good at this moment. I want to raise a couple of the main concerns that I have. Dr. Todhunter and I have not had any dealings so far. He has been with EPA for several months and, although he has been a consultant to the Administrator in a quasi-official capacity, he is effectively running the toxic

program. During that time a number of things have happened which have caused a very serious concern.

He spoke in his statement about being qualified in accordance with what the statute requires of an assistant administrator. The statute says that the Assistant Administrator must be somebody especially qualified to direct a program concerning the effects of chemicals on human health and on the environment. Although he mentioned those two considerations, he also mentioned a third one concerning impact on industry. I am the first to agree that impact on industry has to be taken into consideration, but it should not be the predominate consideration in the toxic substances program, as it is threatening to become. I can support that allegation by outlining a number of developments that are occuring at EPA.

First of all, during and after the Carter administration, the staff of the Office of Toxic Substances made a recommendation for the Agency to take expedited action on two cancer-causing substances, formaldehyde and di-(ethylhexyl)phthalate, commonly known as DEHP. Those recommendations were sent to the Acting Administrator who wouldn't sign them because Mrs. Gorsuch was coming in the next week. To this day, those recommendations have not been acted on. Yet there are statutory deadlines running because those are high priority chemicals.

Instead of acting on those recommendations, the Deputy Administrator held a series of secret science courts at which only industry representatives and EPA staff were included. We were entirely excluded from these meetings although our interest in the two chemicals is widely known since we had served EPA with a 60-day notice of intent to bring suit.

At the end of those meetings, which Dr. Todhunter participated in, the Agency made the tentative decision not to proceed with regulation of either of those chemicals. There is a memo from Dr. Todhunter's staff to him and that memo suggests a radical change in the Agency's policy on regulating carcinogens. The tentative decision on formaldehyde suggests that animal data are not good enough, that human data are necessary and that the decision is to not proceed with anything on formaldehyde until they have some human evidence.

I would like to read to you a short statement by Dr. Arthur Upton who is head of the NYU Institute on Environmental Medicine:

> If the carcinogenicity of formaldehyde is ignored, it would mean that no agent could be regarded as carcinogenic in the absence of positive evidence in humans. We hope that Federal regulatory agencies will regard formaldehyde as a carcinogen and find ways to continue its important commercial and scientific uses in a sensible safe fashion.

That is what TSCA is all about. EPA, apparently with the approval and involvement of Dr. Todhunter, is not going to proceed on this one substance which the toxics program itself in the past, after a lengthy period of study, recommended for priority regulatory action.

Again, the exclusion from these meetings of the public and interested scientists involved in these issues out in the rest of the world says to me that the toxic program is in danger of being captured by the regulated industry. When the Agency goes only to the regulated industry for information about the toxic effects of a substance,

they are only going to be getting one piece of information on the subject.

The second example, also going on at the time that Dr. Todhunter has been running the program de facto, involves a petition from the Chemical Manufacturers Association for the establishment of broad exemptions for new chemicals from the premanufacture notification program. I don't know how familiar you are with the way that program has been running, but manufacturers of new chemicals have to give notice to EPA 90 days in advance of commercial manufacture, detail the name of the chemical and the uses, and provide any data on toxicity and environment effects if they have it. There is no requirement that they generate data on toxicity.

Since April 1979 when that program got underway, the Agency has received notices about 66 percent of which had no information whatever on toxicity. Since there is a criminal penalty for withholding such information if it exists, it is clear the companies are simply not testing their chemicals to generate toxic data. The notices continue to come in at the rate of about 700 a year, still with the vast majority of them not having any data on toxicity. The Chemical Manufacturers Association has a petition before EPA that would exempt about 75 percent of new chemicals from the premanufacture notification requirements. The statute allows for such an exemption to be granted by EPA upon application and by rule, although I don't think it envisions 75-percent exemptions, but there is nothing improper in the filing of the petition. What has happened however, is that EPA has engaged in private negotiations with the Chemical Manufacturers Association, setting up secret CMA and EPA work groups to develop the exemption rule.

Our interest is well known to EPA, but we have not been included. We have asked to be included. I find this procedure to be outrageous. I would like to hear from Dr. Todhunter about whether he approves of this procedure. It is not what TSCA envisioned. "By rule" means public notification, and public comment, where anybody who has anything to say on the subject has an opportunity to say it.

In the past EPA has been very open in the development of TSCA rules. It is a complicated area, so they have had a lot of preproposals, and public meetings, and anybody who had anything to say had an open door to EPA. That door isn't open now to anybody but industry, from our point of view. We are not being invited, we are not being told, we have not been given the opportunity to participate, and our chances to influence that final rule are quite miniscule.

The apparent reversal of longstanding EPA policy on regulating carcinogens, by requiring a much higher standard of proof, that is, evidence of cancer in humans before taking action, is exemplified by the tentative decision on formaldehydes. I said in my statement that the Agency can change policy if they want to. I think that in the important area of regulating carcinogens, however, it ought to be done openly and publicly and every scientist in the country or in the world who has anything to say about that should have an opportunity to do so. That isn't the case.

The last point I wanted to make involves another section of TSCA which requires testing of new chemicals or of existing chemicals. The statute sets up an interagency committee to make recommendations to EPA for testing of chemicals that are widely used and possibly hazardous but have not been adequately tested. The Agency has 1 year from the receipt of the recommendations to either issue testing rules or decide that testing is not necessary. EPA has not implemented that provision properly and NRDC sued and won a decision against the Agency which puts them on a time schedule to initiate testing requirement for the priority chemicals or within the 1-year statutory deadline to explain why testing is not necessary.

EPA has not promulgated a single rule for any priority chemical to be tested. Instead it has launched into another series of private negotiations with industry to devise voluntary testing schemes. TSCA envisioned that the chemical industry would do their own testing, but the priority chemicals which are now on the court-ordered schedule are going to be the subjects of voluntary testing schemes instead of testing rules. This means that none of the statutory protection that a testing rule would provide will actually come into play. As a result, the testing will not have to be completed by any special time and there will be no public review of the proposals unless EPA decides to do that voluntarily.

Those manufacturers of new chemicals whose chemicals fall in the category that would have been covered in a test rule, according to the way the statute is written, then could not go forward with manufacture unless testing was done and data submitted. That provision wouldn't apply. The requirement for notification to foreign governments of the export of a substance under test, the requirement that receipt of data be noticed in the Federal Register and the data made available to the public, all those provisions are inoperative when a voluntary scheme is approved by the Agency in lieu of testing rules.

I think that the voluntary approach is a perfectly suitable procedure if a company wants to test a chemical; it is not an appropriate procedure when these are priority chemicals recommended to the EPA by the expert interagency testing committee over which the Agency was sued and for which the Agency is now on a court-ordered schedule to set testing rules or decide testing isn't necessary.

That is the way the toxics program at EPA is proceeding apparently with Dr. Todhunter's approval. I would like some explanation of Dr. Todhunter's position of these issues before the committee recommends its confirmation. I am quite concerned about the future of the Toxic Substances Control Act program as it appears to have come to a halt. The statute envisions that the public will be broadly involved in implementation of it and that is not the case right now.

Thank you.

Senator STAFFORD. Thank you very much for being here and helping us this morning. We will see that your testimony is called to the attention of the other members of the committee.

Dr. Todhunter, some charges in effect have been made here. We won't ask you to respond to them now, but I would suggest at your

earliest convenience you respond to them in writing to the committee, and I would ask that copies of any and all documents relating to the formaldehyde or DEHP decisions be submitted to the committee together with a list of those attending at such meetings, or that those records be made available to our committee staff at EPA.

There being nothing further, unless there is some other witness here I am unaware of, the committee meeting on the hearing of Dr. Todhunter is adjourned.

[Whereupon, at 10:45 a.m., the committee recessed, to reconvene subject to the call of the chair.]

[Mr. Todhunter's résumé, responses to committee questions, responses to testimony of Ms. Warren, a letter from the American Paper Institute-National Forest Products Association, and Ms. Warren's prepared statement follow:]

John A. Todhunter, Ph.D.

Assistant Administrator-Designate
Office of Pesticides and Toxic Substances
Environmental Protection Agency

Dr. John A. Todhunter, nominated by President Reagan to serve as Assistant Administrator for Pesticides and Toxic Substances at the Environmental Protection Agency, will be managing the Agency's pesticides and toxic substances programs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Toxic Substances Control Act (TSCA); directing enforcement of these laws; and promoting coordination of all Agency programs engaged in toxic substances control activities.

Education and Experience:

Ph.D. (Biochemistry) 1976; University of California, Santa Barbara, California
From 1974 - 1976 held positions of Teaching Assistant, Research Assistant, and Regent's Fellow.

Master of Science (Bio-organic chemistry) 1973; California State University, Los Angeles, California
From 1972 - 1973 held rank of Instructor.

Bachelor of Science (Physical organic chemistry) 1971; University of California, Los Angeles, California
Laboratory Assistant in the laboratory of Dr. W. F. Libby.

Professional Experience:

The Catholic University of America, Washington, D. C.; 1978 - Present

Chairman of the Biochemistry Program. This program spans the departments of biology and chemistry which have 20 faculty and serve over 100 students, graduate and undergraduate.

Faculty appointment as assistant professor of biology. Dr. Todhunter's administrative duties included resource prioritization and allocation, curriculum, inter-departmental coordination, and day to day management of the Biochemistry Program. He taught graduate courses in the areas of biochemical physiology, enzymology, molecular biology, and research methodology and was an Associate of the cell biology, microbiology, and medical technology programs.

Roche Institute of Molecular Biology, Hoffman LaRoche Inc., Nutley, New Jersey; 1976 - 1978

Fellow in the Department of Biochemistry.
In 1976 Dr. Todhunter began research which he continued throughout his tenure on the Catholic University faculty. This research concerns the effects of drugs and toxic substances on enzymes which contribute to the production of ribosomal RNA and on genes at the molecular level.

Related Activities:

State of Maryland, Member, Hazardous Waste Facilities Siting Board, appointed by Governor Harry Hughes to term 1980 - 1981.
Office of the President Elect; Group Leader - policy/program; Consumer Product Safety Commission transition team, 1980 - 1981.
Catholic University of America, Institutional Radiation and Laboratory Safety Committee, 1979 - 1981.
American Council on Science and Health, New York; member, Board of Scientific Advisors, 1978 - 1981.
Catholic University of America, member, Institutional Review Board for the Protection of Human Subjects, 1978 - 1981.

Professional Recognitions:

Biographical listings in American Men and Women of Science; Who's Who in the East; 15th edition
Hoffman, LaRoche Inc., Nutley, New Jersey: Recipient of Roche Fellowships (1976, 1977)
University of California, Santa Barbara, Department of Chemistry: Recipient of Dr. B. R. Baker Memorial Fellowship (1976)
Uiversity of California, Board of Regents: Recipient of University of California Regent's Fellowship (1975)
California State University Alumni Association: Recipient of Graduate Award in Chemistry (1974)

Biographical Information:

Born Cali, Columbia, South America, October 9, 1949
U. S. citizen (by birth); hispanic ethnic.
Married, two children

87-258 O—82——4

Honorable Robert T. Stafford
Chairman
Committee on Environment and Public Works
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

I appreciate the opportunity to respond to Senator Max Baucus' questions dated October 23, 1981. I understand that these responses will be incorporated into the record of my October 16, 1981 nomination hearing.

1. Question:

According to an article that appeared in the Washington Post on October 8, 1981, you and Dr. M. Adrian Gross, chief scientist with the Hazard Evaluation Division, differed sharply in your assessments of the risk to human health posed by the use of ethylene dibromide (EDB) as a pesticide. Could you account for the widely differing evaluations you and Dr. Gross arrived at with respect to the incidence of cancer in humans that could occur as a result of using EDB in combating the Mediterranean fruit fly in California?

Answer:

I am, in my capacity as an expert consultant to the Administrator, in full professional agreement with the risk assessment of ethylene dibromide (EDB) carried out by the Carcinogen Assessment Group (CAG) of EPA's Office of Research and Development. This assessment has also been judged adequate by EPA's FIFRA Science Advisory Panel (SAP). Dr. M. Adrian Gross disagrees with the CAG risk assessment and, by extension, any risk estimates done by staff of the Office of Pesticide Programs (OPP) which are based on that CAG assessment. This is the sole basis on which Dr. Gross and I can be said to differ: I agree with staff's risk assessment, he does not.

2. Question:

Gamma ray irradiation has been mentioned as an alternative should the use of EDB be banned. Can you comment on the feasibility of this process and any risk it might pose to human health?

Answer:

The FIFRA Science Advisory Panel has written, in March of this year, that they consider it premature to predict when irradiation will be available as a viable means to treat

citrus fruits. Theoretically, the treatment should be feasible but the practical considerations need to be worked out. FDA, also, has unresolved questions as to the effect of the treatment on the texture, appearance, shelf-life, and nutrient quality of the fruit. It is doubtful that required FDA approvals would be given unless these questions were resolved. As to the human health risks (leaving aside the FDA concerns), there are none to consumers but there may be some to operators of the treatment process. These latter risks could probably be reduced to insignificant levels by appropriate work practices.

3. Question:

The Environmental Protection Agency is scheduled to issue a final position on the proposed ban of EDB in December. Can you describe where the risk assessment analysis for this determination originates?

Answer:

The risk assessment for the EDB Rebuttable Presumption Aganist Registration (RPAR) originated from the CAG and uses residue and exposure data supplied by OPP staff.

4. Question:

Would you comment on any administrative experience you have accrued professionally that you feel qualifies you for the position of Assistant Administrator of the Office of Pesticides and Toxic Substances?

Answer:

My administrative experience has come in both the academic state and private sectors. I have served for three years as Chairman of the Biochemistry Program at Catholic University. In this position I had responsibility for administration, curriculum oversight, course scheduling, and recruiting. This was in addition to direction of my own research program which was funded by the National Institutes of Health, performing cooperative research in plant regulators with USDA scientists, and coordinating gene toxicology work performed by the University under DOD funding. I saw service on University-level review boards on protection of human subjects and chemical and radiation safety.

I was also appointed - under a provision of Maryland law requiring a representative of the scientific community - to the Maryland Hazardous Waste Facilities Siting Board by Governor Hughes. This appointment provided me with the opportunity to obtain valuable experience in the formulation and promulgation of environmental regulations.

I have also been a private businessman as a partner in an electrical/electronic contracting business. This provided me with hands-on experience in cash-flows, personnel issues, and contracts.

I believe the sum of my experience qualifies me, with respect to administrative capability, for the position to which I have been nominated.

Thank you for this opportunity to respond to Senator Baucus' questions.

Sincerely yours,

John A. Todhunter, Ph.D.

October 30, 1981

Honorable Robert T. Stafford
Chairman
Committee on Environment and Public Works
United States Senate
Washington DC 20510

Dear Mr. Chairman:

I am pleased to respond, at your request, to testimony presented by Ms. Jacqueline M. Warren on behalf of the Natural Resources Defense Council (NRDC) at my confirmation hearing on October 16, 1981. I will proceed through Ms. Warren's testimony in sequence and attempt to respond to NRDC's concerns.

(1) A Perceived Pro-Industry Bias of the American Council on Science and Health (ACSH)

The testimony describes the American Council on Science and Health (ACSH) as "avowedly pro-industry". A major NRDC concern appears to be my prior affiliation with this group.

The quality of the science done by ACSH is well recognized--every study done is first reviewed internally by 10-15 reviewers who are Ph.D.s and M.D.s and then externally by internationally recognized specialists in the subject of the study. As a result of this extensive peer review, ACSH has taken "anti" industry positions on a number of occasions including active campaigns against the cigarette industry; a public stand against the extended use of drug containing estrogens in post-menopausal therapy due to the risks of uterine cancer; and a public stand against excessive consumption of alcohol by pregnant women. Nearly one year before the United States Surgeon General recommended that pregnant women limit intake to 1 oz. of alcohol per day, ACSH issued the same recommendation in the face of the liquor industry suggestion that a 3 oz. per day limit was more reasonable. In addition, a 1981 ACSH report on health risks due to pollutants in air was published as both a majority and a minority statement to reflect the lack of consensus among the authors. This represents, I believe, the high degree of intellectual honesty of ACSH.

(2) Secret "Science Courts" Attended Only by Industry

Ms. Warren expresses concerns that a tentative decision not to regulate formaldehyde and DEHP was made in a series of "secret science courts" before Deputy Administrator Dr. Hernandez and that these meetings included only representatives of the affected industry and EPA staff. You have, under previous cover, complete

documentation of these two meetings; therefore I will not reiterate those factual details here.

I would like to add to the factual record, however, that Dr. Hernandez did not initiate contact with the Formaldehyde Institute or with industry groups associated with DEHP. Rather, these groups requested an opportunity to meet with Dr. Hernandez to discuss the available scientific data on the mechanism and possible carcinogenicity of formaldehyde and DEHP. As the participant list indicates, attendance included scientists from the Office of Science Advisor to the President, the National Cancer Insititute, the National Academy of Sciences, the National Toxicology Program and independent research facilities. These scientists had a full voice in these briefings.

(3) Broad Exemptions From Premanufacture Notification Requirements

The Chemical Manufacturers Association (CMA) has filed a petition for a four part exemption for certain chemical classes: high molecular weight polymers, low volume chemicals, enclosed process intermediates, and site restricted intermediates. The receipt of this petition is a matter of public record and copies can be obtained through the Agency. The petiton is under technical review and, of necessity, technical dialogue with the petitioners is on-going so as to clarify certain technical aspects of their request. In some instances, the petitioners may need to discuss matters involving Confidential Business Information (CBI) with EPA staff who have been cleared to discuss such material. The privileged status for CBI was wisely written into the law by Congress and is the cornerstone of EPA's ability to obtain the information it needs to do its job. I am sure that if other groups request meetings to discuss CMA's petition with EPA's reviewing staff, such meetings would be welcomed.

Finally, it should be pointed out that all exemptions under TSCA Section 5(h)(4) are granted by rule. The rulemaking procedures outlined in the Administrative Procedures Act (A.P.A.) will properly and adequately involve the public in the final decision making. I support nothing less than full public involvement in this important rulemaking.

(4) Apparent Reversal of Long Standing EPA Policy Regarding Regulation of Cancer-Causing Substances

I don't believe that current EPA actions reflect a reversal of standing EPA policy. As I pointed out in my statement before the Committee, under my leadership I would expect OPTS (Office of Pesticides and Toxic Substances) to continue to rely on animal data to assess the potential toxicity of specific chemicals. As a professional scientist versed in pharmacology, toxicology, physiology, and biochemistry I fully realize that this is the

best approach.

What may change is OPTS' reliance on a single curve fitting computer model to estimate risks and exposures. Several models may be used and those which best describe and fit the data, case-by-case, will be used to estimate relative risk. I believe that OPTS should consider mechanisms of action, physiological differences, pharmacodynamics, and the now well accepted distinction as to different classes of carcinogens. This is a public responsiblity--to present the best possible and most up-to-date scientific basis for decision making.

(5) Inadequate "Voluntary" Testing Schemes are Being Substituted for Testing Rules

The development of testing programs is technically a very involved exercise. It must also be open ended because every well designed test scheme uncovers new questions and is formed, in essence, by a series of decision modules. With regard to public involvement in the development of voluntary test schemes, the Agency has generally held, and I agree, that public input is especially useful during the comment period following a test plan proposal.

The first major voluntary scheme to come to fruition since I became a consultant to the Administrator is the test plan for a alkyl phthalates which had been recommended for further study by the Interagency Testing Committee. This plan took 4-5 months to negotiate (I was not involved) as opposed to 1-2 years estimated for test rules promulgated under formal rule making procedures. The plan was in final draft proposal August 25 and the public was so informed. Two weeks later at a public meeting, NRDC asked OPTS for more time to review the plan. Even though EPA was required to publish a decision concerning testing for one of the phthalates by October 24,1981, because of it's request, NRDC was given additional time beyond that date to comment. I believe that voluntary testing represents a commitment to efficient resolution of public health concerns. The process followed above also illustrates a willingness to accomodate the concerns of interested parties. To the extent that well-designed, publicly scrutinized voluntary testing programs can act to speed up the entry of test data into the public domain, then I think such efforts are laudable.

I believe I have responded to all the concerns expressed by Ms. Warren and NRDC. Again, I appreciate this opportunity to clarify these issues.

Sincerely,

John A. Todhunter, Ph.D.

API/NFPA Environmental and Health Program

American Paper Institute
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National Forest Products Association
(202) 797-5800
1619 Massachusetts Ave., N.W., Washington, D.C. 20036

October 15, 1981

The Honorable Robert T. Stafford
Chairman
Committee on Environment
and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Your committee has before it the nomination of John A. Todhunter to be the Environmental Protection Agency's Assistant Administrator for Pesticides and Toxic Substances. On behalf of the American Paper Institute and the National Forest Products Association, I wish to express our strong endorsement of Dr. Todhunter's nomination.

Our two trade associations and the over 2,000 companies which they represent--companies that own and manage forest lands and manufacture pulp, paper, lumber and other solid wood products--are fully committed to the safe handling, use and disposal of potentially harmful chemicals. We believe Dr. Todhunter shares these concerns and that his confirmation would go a long way toward upgrading the role of rigorous and careful scientific inquiry in regulatory decision-making, a goal we have long endorsed.

I would appreciate your including this letter in the confirmation hearing record. Thank you.

Very truly yours,

Michael C. Farrar
Vice President and Director
Environmental and Health
Program

cc: Senate Committee on Environment
and Public Works

Natural Resources Defense Council, Inc.

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TESTIMONY OF

JACQUELINE M. WARREN

NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE

UNITED STATES SENATE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

OCTOBER 16, 1981

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Introduction

The Natural Resources Defense Council (NRDC) is a national non-profit environmental organization supported by 45,000 members who are dedicated to the wise use of the nation's land and water resources, and to the protection of human health and the environment. Since its inception in 1970, NRDC staff attorneys and scientists have been involved in administrative, legal and legislative efforts to control involuntary exposures to toxic and especially cancer-causing substances in the environment. Among other statutes, NRDC has monitored the EPA's implementation of the Toxic Substances Control Act (TSCA) since its passage in 1976.

Before assuming my present position as director of NRDC's Toxic Substances Project in 1980, I was a staff attorney for the Environmental Defense Fund, and I have worked on toxic substances issues since 1973. In addition to my involvement with the passage and implementation of TSCA, I have also carefully followed EPA's implementation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as well as a number of other environmental statutes addressing the problem of toxic substances control. Since 1979, I have been a member of the EPA's Administrator's Toxic Substances Advisory Committee, and I have been an outspoken critic of the slow pace of EPA's prior administration of TSCA before the Advisory Committee, in the press,

before Congressional committees, and in the courts. I therefore welcome this opportunity to present to this Committee my concerns about the nomination of Dr. John Todhunter to be Assistant Administrator for Pesticides and Toxic Substances.

TSCA was passed in response to repeated disclosures about the severe adverse health, environmental and economic damage inflicted by such widely used substances as PCBs, kepone, vinyl chloride, PBBs and asbestos, to name but a few. The Act was intended to remedy the lack of legal authority to prevent such problems from arising, or to deal adequately with them after the fact of injury or serious risk was established.

The clearly-stated overriding purpose of TSCA is to prevent unreasonable risks of injury to health and the environment from exposure to toxic substances. The basic objectives of the law, as set forth in section 2, are that adequate data on the effects of chemicals should be developed by those who produce them; that EPA should have adequate authority to regulate chemical substances which present an unreasonable risk of injury to health and the environment; and that undue or unnecessary burdens on commerce and innovation should be avoided in "fulfilling the primary purpose

of the Act to assure that such innovation and commerce in chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment". (TSCA §2(c)).

To achieve these purposes, Congress provided EPA the authority to require that chemicals be tested to determine whether they are hazardous; to restrict or even prohibit their manufacture and use in appropriate circumstances; and to screen new chemicals to identify potential "bad actors" before, rather than long after, their entry into commerce. Moreover, to ensure that the objectives of the Act would be achieved, Congress specified in §26(g) of TSCA that the Assistant Administrator be "a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment". While Dr. Todhunter's background in biology and biochemistry certainly provides him with appropriate technical qualifications for the position, his prior affiliation with the avowedly pro-industry American Council on Science and Health, and the dramatic policy reversals which are occurring in the TSCA Program, apparently under his auspices, cause us to have serious reservations about whether he is in fact "especially qualified to direct a program concerning the effects of chemicals on human health and the environment".

Recent events at EPA suggest that the previously painfully slow process of requiring testing of suspected "bad actor" chemicals under §4 of TSCA, screening new chemicals under §5, and controlling chemicals found to pose unreasonable risks of injury to health or the environment under §6, has ground to a complete standstill. Instead of moving to implement these statutory provisions more effectively, the Agency is focusing much of its efforts on finding ways to exempt the chemical industry from those relatively few TSCA requirements that are now in effect. In this undertaking, the regulated industry is playing a predominant role while the public is virtually entirely excluded from the process.

The following examples well illustrate our concerns:

1. Secret "Science Courts" Attended Only By Industry

In a series of secret "science courts" before Deputy Administrator John Hernandez, including only representatives of the affected industry and EPA staff, the Agency has tentatively decided not to regulate two widely-used carcinogenic chemicals, formaldehyde and di-(ethylhexyl) phthalate (DEHP), earmarked by the prior Administration for expedited action. Although NRDC's interest in both chemicals is well-known to EPA, having been announced in a 60-day letter stating our intention to sue the Agency if action on them is not

forthcoming, neither we nor any other non-government or non-industry groups, such as highly respected scientists at the New York University Institute or Environmental Medicine, who are conducting research on the health effects of formaldehyde, were informed or included in any of the meetings. The propriety of such a procedure, in which EPA officials meet only with industry lawyers and scientists, and then decide to reverse the earlier recommendations of the TSCA Program staff that expedited action against those chemicals is warranted, is highly questionable. It is the subject of a hearing next week before the House Government Operations Committee. In all likelihood, those secret, biased procedures will also be the subject of a lawsuit against EPA. While Dr. Todhunter's role in initiating these meetings is unknown to us, he was present at all of them, and the implication is clear that he saw no impropriety in excluding all but the affected industry from such important decision-making sessions.

In the entire four years that TSCA has been on the books, EPA has been very open and accessible to all interested parties. Now the Agency appears to be closed to all points of view except those who have a vested interest in avoiding regulation. To our knowledge, Dr. Todhunter has not made any public statement on this issue, and his silence suggests that further proceedings of this kind are likely to follow

during his tenure as Assistant Administrator. Since TSCA provides numerous opportunities for broad public oversight and involvement in decision-making under the Act, Congress clearly intended the law to be administered openly. To date, under Dr. Todhunter's leadership, the TSCA Program has been proceeding in a manner that directly contravenes that intent.

2. Broad Exemptions from Premanufacture Notification Requirements

A second example of bias and exclusion of the non-industry public from any opportunity to shape or influence EPA policy is the effort presently underway to develop a rule creating broad exemptions of new chemicals from the premanufacture notification provisions of §5.

The purpose of premanufacture notice (PMN) to EPA is clearly stated in the Conference Report on TSCA:

> The provisions of the section reflect the conferees' recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. (H.Rep.No.94-1679, 94th Cong.,2d Sess.65(1976)).

EPA has been receiving PMN notices since April 1979. At the end of 1980, Agency figures showed that a large majority (66%) of the notices were submitted with no data whatever on

the toxicity of the new chemical. More than 50% of the deficient notices came from large companies with sales greater than $500 million dollars a year. Subsequent figures indicate that the number of notices submitted to EPA without toxicity information is continuing at the same level. These statistics suggest that the PMN program as currently implemented is not encouraging the voluntary development of premanufacture health and environmental effects data. On the contrary, it appears that even the largest chemical producers, who can best afford to test their products prior to marketing, are not doing so in large numbers.

EPA's Notice Review Branch, which receives the PMNs, is seriously understaffed and overburdened.* Moreover, the absence of toxicity data means that health and environmental effects assessments must be based upon data on similar chemicals, to the extent that EPA staff can identify such data. The net result is that EPA, rather than the chemical industry, has been bearing the burden of locating data relevant to the potential hazards of new chemicals -- and that the majority of new chemicals are

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*The Branch is budgeted to review competently 200 notices a year, but is currently receiving 14 PMNs a week, a rate which will bring 700 PMNs in for review in 1981. The Administration's budget and personnel cuts will not permit an increase in staff to review adequately the increased number of submissions.

entering the marketplace without an adequate assessment of the hazards they may pose to health and the environment.

Although EPA, on January 27, 1981, published as a policy statement a recommended approach to premanufacture testing, such testing is not required under TSCA. The policy statement endorses and recommends that chemical producers develop the Minimum Premarket Data set now provisionally agreed upon by the 24 countries of the Organization for Economic Cooperation and Development as an appropriate starting point for the prediction of risk of new chemicals. The OECD Premarket Data Set is almost identical to the premarket testing scheme adopted last year and currently being implemented by the member countries of the European Common Market. Such a testing scheme is not a requirement in the United States, however. As the figures graphically demonstrate, in the majority of cases, chemical producers in this country are not voluntarily testing their new chemicals to identify adverse health or environmental effects. Instead, four years after TSCA was enacted, the chemical industry in the United States generally appears to be conducting business as usual, and continuing to use the workplace, the general public and the environment as a testing laboratory for determining the adverse effects of their products. It is also clear that the industry's frequent claim that testing requirements are not needed because new chemicals are being

adequately tested, is simply not true.

In order to make current industry practice wholly legitimate under TSCA, several chemical industry trade associations, such as the Chemical Manufacturers Association (CMA), the Society of Plastics Industry, and the Synthetic Organic Chemical Manufacturers Association, among others, have petitioned EPA under §5(h)(4) of TSCA for exemptions from the requirement of submitting PMNs for their new chemicals. Although no notice of receipt and availability of the CMA petition has ever been published, it has become the focus of an extensive internal effort at EPA to develop a rule that would exempt an estimated 75% of new chemicals from the PMN requirements of §5. Secret EPA-CMA workgroups are being set up to develop such a rule, and CMA has even suggested a timetable for EPA for completion of the workgroups' tasks and intra-Agency review, and for publication of the proposed rule in the Federal Register. Other interested members of the public are not included in the workgroups, whose deliberations are completely secret.

Not only does this procedure appear to violate the Federal Advisory Committee Act, but it also epitomizes the approach of the current Administration to public participation in Agency decisionmaking in general. Very little information is coming out of EPA, and only carefully preselected, i.e., industry, information is coming in. When

the exemption rule developed by this secret procedure is published as a proposal, it will represent the joint agreement between EPA and the chemical industry, and it is highly unlikely that any comments submitted by others during the pro-forma rulemaking will have any impact on the final exemption rule. Thus, the current leadership of EPA has substituted the openness of its predecessors for secrecy and back-room negotiations with the chemical industry, an approach which also directly contravenes both the letter and spirit of TSCA. In our view, this entire process is a classic illustration of the "captive agency" syndrome, in which the regulated industry exercises undue influence over the regulatory agency to the detriment of the public at large. This questionable approach also apparently is proceeding with Dr. Todhunter's knowledge and approval.

3. Apparent Reversal of Long-Standing EPA Policy Regarding Regulation of Cancer-Causing Substances

EPA's tentative decisions not to regulate formaldehyde and DEHP are not only based exclusively on industry-provided information, but they also represent a 180-degree turnabout in the Agency's long-standing approach to the regulation of carcinogenic substances. Apparently adopting the views advanced by the Formaldehyde Institute, the TSCA Program has reversed the prior staff recommendation, and is now recommending against expedited regulation of formaldehyde under §4(f) of TSCA. The basis for this change is that although

formaldehyde is a carcinogen, and very widely-used, there is not sufficient evidence of harm to humans to warrant action. In other words, preventive action which would have resulted from application of existing EPA policy on regulation of carcinogens is not being recommended. Instead, action will be deferred until -- if ever -- more conclusive proof of harm to human health can be demonstrated.

Although in my experience, affected industries have consistently argued in favor of conclusive proof of harm to humans as a prerequisite to regulation of cancer-causing substances, none of the federal regulatory or scientific bodies has ever espoused this approach in the past because it is insufficiently protective of public health. Moreover, actions to prevent harm rather than merely to react after the fact have been uniformly upheld by the courts:

> Courts have traditionally recognized a special judicial interest in protecting the public health"where the matter involved is as sensitive and fright-laden as cancer! Where the harm envisaged is cancer, courts have recognized the need for action based upon lower standards of proof than otherwise applicable.

Certified Color Manufacturers Association v. Mathews, 543 F.2d 284 (D.C. Cir.1976), quoting EDF v. EPA [DDT], 465 F.2d 528, 538 (D.C. Cir. 1972).

The rationale for this approach is simple. As one court stated in upholding EPA's 1977 prohibition on the further discharge of PCBs into water under the Clean Water Act:

> What scientists know about the causes of cancer is how limited is their knowledge. [I]t may take decades for human exposure to carcinogens to result in cancer; in the meantime, the case for inferring a cancer danger with respect to an incompletely understood substance is vigorously debated. If regulation were withheld until the danger was demonstrated conclusively, untold injury to public health could result.

EDF v. EPA, 598 F.2d [illegible] (D.C.Cir. 1978).

The policy reversal reflected in the tentative decisions not to regulate formaldehyde and DEHP represents the espousal by the TSCA Program of industry arguments regarding the regulation of carcinogens which have been repeatedly rejected in the past for the reasons stated above. While any agency is free to change policy directions, in this critically important area, such a decision should be made openly, with input from as broad a cross-section of the scientific community and the public as is possible. It should not be done secretly, in back-room meetings with industry representatives. Here again, Dr. Todhunter's role is unclear, but the approach is the same one advocated by the American Council on Science and Health.

4. Inadequate "Voluntary" Testing Schemes are Being Substituted for Testing Rules

Section 4 of TSCA requires EPA to propose test rules or decide that testing is not necessary for chemicals designated as high priority for testing by a committee of experts, the Interagency Testing Committee (ITC), within one year of such designation. Chemicals recommended by the ITC are selected because they are produced and used in very large quantities and

have exposure potential and biological or chemical properties that are likely to pose risks of cancer, gene mutations, birth defects, or environmental damage. When EPA failed to act on the first recommended priority chemicals within the statutory period, NRDC brought suit. In February 1980, a United States District Court ruled that EPA was required to act within 12 months after receiving the ITC's recommendations, and in January 1981, placed EPA on an expedited schedule for action on the listed priority chemicals.* According to the schedule, EPA must propose test rules or decide testing is unnecessary for 11 priority chemicals in 1981, 13 in 1982, and 13 in 1983. This schedule is significantly shorter than the seven years EPA initially claimed were needed to dispose of the back-log of ITC-recommended candidates for testing rules.

Although in affidavits to the court, various EPA officials have represented that the deadlines will be met, events in recent months suggest the contrary. Almost a year has passed since the closing of the public comment period on the first testing rules covering three chemicals on the list, but final rules have not been issued. In fact, agency personnel have told NRDC that they have no present plans to issue those rules in final form. Instead, ex-tensive negotiations are underway between EPA and various industry associations regarding the development of voluntary testing schemes in lieu of testing rules under §4 for the priority chemicals.

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*NRDC v. Costle 14 ERC 1858, __F.Supp.__(S.D.N.Y.1980)

NRDC recognizes that voluntary testing by the manufacturers of chemicals is an objective of TSCA, and we would welcome the widespread acceptance of this responsibility by the chemical industry. Voluntary testing schemes for the priority chemicals on the court-ordered schedule, however, raise issues that voluntary testing of other chemicals do not. The priority chemicals are those suspected by an expert committee of posing potential hazards to health and the environment, and for which specific tests have been recommended. They are covered by one of the few action-forcing provisions of TSCA, §4(e), and decisions to issue test rules for them trigger numerous other statutory requirements. For example, development of test rules involves extensive public input (notice-and-comment rulemaking), Federal Register notice and public access to data produced pursuant to a testing rule (§§4(d) and 14(b)),submission of test data with a PMN (§5(b)); enforceable laboratory procedures and testing deadlines (§15); and notification to foreign governments of the export of a substance subject to a test rule (§12).

Acceptance by EPA of voluntary testing schemes developed by industry as a substitute for rulemaking will result in industry testing commitments that are not enforceable, may not be adequately comprehensive, may never be completed, and from which public oversight and involvement are entirely absent. EPA could correct some of these deficiencies by supplementing the voluntary programs with rules requiring necessary additional testing, by imposing deadlines for completion of the tests through enforceable con-

tracts, and by involving the public to the same extent as §4 provides. While EPA has held a public meeting on the first two voluntary testing proposals, it is unclear how much public involvement will be provided in the future. It is also unclear whether EPA will impose additional requirements to cover deficiencies that the Agency acknowledges are in the proposed programs, although specifics have been impossible to obtain.

In summary, NRDC views the open-ended and admittedly insufficient voluntary testing approach as a poor substitute for the test rules TSCA intended the Agency to promulgate for the priority chemicals. While incentives for industry to initiate voluntary testing should be encouraged, we do not believe that the priority chemicals will ever be adequately tested unless EPA issues the first testing rules in final form, and attaches to the voluntary proposals the guarantees of expedition, completion, adequacy of comprehensiveness, public involvement, and connection with other TSCA provisions that Congress intended in §4(e). Here again, we question Dr. Todhunter's commitment to achieving the objectives of TSCA, including ensuring that the public is provided the opportunities for involvement in TSCA decisionmaking that §4 and other sections of the statute provide.

The public is entitled to expect that federal regulatory officials entrusted with the grave responsibility of protecting

their health will be open-minded, and will, if they err at all, err on the side of safety. In this regard, Dr. Todhunter's association with the American Council on Science and Health raises serious questions about his ability to handle in an unbiased manner such issues as the regulation of carcinogens. As a principal science advisor to the Council, he is necessarily identified with its outspoken efforts to disparage and discount public concerns about the safety of various chemicals, pesticides, food additives and the like. Moreover, he has so far made no public effort to dissociate himself from their single-mindedly pro-industry stance on controversial health and safety issues. Coupled with the policy changes underway in the TSCA Program under his de facto supervision, the unavoidable conclusion is that public health may not be adequately protected against harm from toxic substances during his term as Assistant Administrator. In the absence of some reassurance that Dr. Todhunter will carry out his responsibilities in a manner that accords more concern to health protection and somewhat less to the impact on industry, NRDC cannot support this nomination.

It is abundantly clear that this Administration does <u>not</u> have a mandate from the American people to weaken the nation's environmental and health protection statutes. A series of recent public opinion polls confirm that there is overwhelming support for continued and strengthened

efforts to protect health and the environment, especially in the area of toxic substances control. We would therefore urge this Committee to ensure that the promise of TSCA will be realized rather than further frustrated in the coming years, and to withhold confirmation of Dr. Todhunter until his biases are throughly explored, and he publicly declares his commitment to achieving the health and environmental protection objectives of the laws he will be charged with administering.

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